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FIRST NAMED APPLICANT ATTY, DOCKET NO. APPLICATION NUMBER FILING DATE 09/227,854 01/11/99 NI EXAMINER 21011 HM22/1108 PAPER NUMBER A ANDERS BROOKES DRAPER. HUMAN GENOME SCIENCES INC 9410 KEY WEST AVENUE ROCKVILLE MD 20850 DATE MATLEO: 11/08/99 This is a communication from the examiner in charge COMMISSIONER OF PATENTS AND TRADEMARKS OFFICE ACTION SUMMARY Responsive to communication(s) filed on ☐ This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 D.C. 11; 453 O.G. 213. A shortened statutory period for response to this action is set to expire month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). **Disposition of Claims** Claim(s) is/are pending in the application. Of the above, claim(s) is/are withdrawn from consideration. Claim(s) is/are allowed. Claim(s) _is/are rejected. Claim(s) _is/are objected to. ____are subject to restriction or election requirement. **Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on _ is/are objected to by the Examiner. ☐ The proposed drawing correction, filed on ___ _is approved disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT Rule 17.2(a)). *Certified copies not received: Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) Notice of Reference Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). Interview Summary, PTO-413 Notice of Draftperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

Serial Number: 09/227854

Art Unit: 1646

DETAILED ACTION

Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-19, drawn to a polynucleotide encoding human chemotactic cytokine I, a vector, a host cell, and a method of producing human chemotactic cytokine I polypeptide, classified in Class 435, subclass 69.5.
- II. Claims 20-24, drawn to human chemotactic cytokine I polypeptide, classified in Class 530, subclass 324.
- III. Claim 25, drawn to an antibody against human chemotactic cytokine I polypeptide, classified in Class 530, subclass 387.9.
- IV. Claims 26 and 30, drawn to an antagonist of unspecified constitution against human chemotactic cytokine I polypeptide and a method of trea..nent comprising the antagonist, Claim and subclass undeterminable.
- V. Claims 27 and 31, drawn to an agonist of unspecified constitution to human chemotactic cytokine I polypeptide and a method of treatment comprising the antagonist, Class and subclass undeterminable.
- VI. Claim 28, drawn to a method of treatment with human chemotactic cytokine I polypeptide, classified in Class 424, subclass 85.1.

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VII. Claim 29, drawn to a method of treament by administering the DNA encoding human chemotactic cytokine I polypeptide, classified in Class 514, subclass 44.

VIII. Claim 32, drawn to a process for diagnosing a disease or a susceptibility to a disease, with the nucleic acid encoding human chemotactic cytokine I polypeptide, classified in Class 435, subclass 6.

- IX. Claim 33, drawn to a diagnostic process for the presence of human chemotactic cytokine I polypeptide using antibodies, classified in Class 424, subclass 145.1.
- X. Claim 34, drawn to a method for identifying compounds which bind to and activate or inhibit a receptor for human chemotactic cytokine I polypeptide, classified in Class 435, subclass 7.2.
- 2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The polynucleotide of invention I can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The polypeptide of invention II can be used as a probe, or used therapeutically or diagnostically, e.g. in screening. The antibody of invention III can be used to obtain the nucleic acid of Group I, and can also be used in diagnostics, e.g. as a probe in immunoassays.

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Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Inventions I and VII or VIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in the production of the human chemotactic cytokine I polypeptide.

Inventions II and VI are relate 'as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product of invention II can also be used as an antigen in the production of antibodies.

Inventions I and IV, V, VI, IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of

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operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions II and IV, V, VII, VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions III and IV-V, VI-VIII, X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions IV and I-III, V-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions V and I-IV, VI-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

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Inventions VI-X are independent and distinct, each from the other, because the methods are

practiced with materially different process steps for materially different purposes and each method

requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired

a separate status in the art as shown by their different classification and recognized divergent subject

matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search

(see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as

indicated is proper.

3. A telephone call was made to J.G. Mullins on 9/19/1997 to request an oral election to the

above restriction requirement, but did not result in an election being made. Applicants requested a

written restriction.

Applicant is advised that the response to this requirement to be complete must include an

election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the

inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R.

§ 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Advisory Information

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Garnette D. Draper, Art Unit 1646, whose telephone number is (703) 308-4232. Examiner Draper can normally be reached Monday through Friday, 9:30 A.M. to 6:00 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Please advise the Examiner at the telephone number above when an informal fax is being transmitted.

PRIMARY EXAMINER

GROUP 1800